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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,033	06/15/2001	Jean-Louis Imbach	06171..105026(NOV 1005)	4301

7590 08/13/2003

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EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 08/13/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicant(s)

09/883,033

Applicant(s)

IMBACH ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 156, 163 and 175-209 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 156, 163, 179, 180, 182-185, 190, 191, 196, 197, 199-202 and 207-209 is/are allowed.
- 6) ☒ Claim(s) 175-178, 181, 186-189, 192-195, 198, 203-206 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

### **Response to Restriction Requirement**

Applicant's election without traverse of Group I, claims 156, 163 and 175-209 in Paper No. 11 is acknowledged.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:  
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 175-178, 181, 186 –189, 192-195, 198, 203-206 are rejected under 35 U.S.C. §102(b) as being anticipated by Weis et al., U.S. Patent No. 5,559,101.

Claims 175-178, 181, 186 –189, 192-195, 198, 203-206 are drawn to 2' deoxycytidine analogs with 3'-O- substituents.

Weis anticipates the claims as it teaches a ribofuranosyl ribonucleoside wherein the 2' may be deoxy and the 3'-O-substituents may be substituted or unsubstituted alkyl of 1-5 carbon(s), anticipating alkyl, methyl, propyl substituents; substituted or

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unsubstituted aromatic ring structure which anticipates substituted aryl, arylsulfonyl and aralkylsulfonyl.

2. Claims 175, 181, 186, 189, 192, 198, 203, 198 and 203 are rejected under 35 U.S.C. § 102(b) as being anticipated by Letsinger, U.S. Patent No. 5,416,203.

Claims 175, 181, 186, 189, 192, 198, 203, 198 and 203 are drawn to 2' deoxycytidine analogs wherein the 3'-O- substituent(s) may be a phosphate prodrug.

Letsinger anticipates the claims as it teaches a 2' deoxycytidine nucleoside analog wherein a lipophilic cholesteryl group is attached to the 3'-O-phosphate group. As applicant notes on p. 43 of the specification, active B-L-prodrugs include phosphate groups substituted with steroids, p. 43, line 2, thus the teachings of Letsinger anticipate the claimed phosphate prodrug 3'-O-substituent.

#### **Allowable Subject Matter**

Claims 156, 163, 179, 180, 182-185, 190, 191, 196, 197, 199-202 and 207-209 wherein the claimed cytidine compound is 3'-O- substituted with an amino acid presents an unobvious modification over the prior art of record, U.S. 5,559,101 and U.S. 5,416, 203.

Howard V. Owens  
Patent Examiner  
Art Unit 1623

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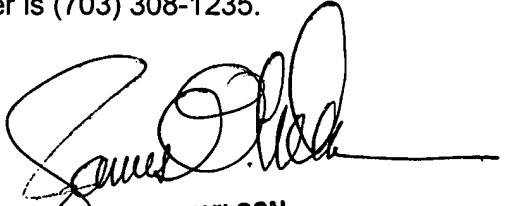
James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**